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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,014	06/27/2001	Hylar L. Friedman	PC10841AMAG	6389

7590 06/03/2003

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	11

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/893,014	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *3,4,7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6 and 9-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on April 2, 2003 in Paper No. 10 wherein claims 13-14 have been amended. Currently, claims 1-20 are pending in this application.

It is noted that Claims 3-4 and 7-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species, of record in the previous Office Action dated November 20, 2002. The claims have been examined insofar as they read on the elected specie, as indicated in the previous Office Action.

Applicant's amendment (amending claims 13-14), flied April 2, 2003 in Paper No. 10 with respect to the objection to claims 13-14 for minor informalities, i.e., the employment of parenthetical expressions, of record stated in the Office Action dated November 20, 2002 has been fully considered and is found persuasive since these parenthetical expressions have been removed. Therefore, the said objection is withdrawn.

Applicant's amendment and remarks filed on April 2, 2003 in Paper No. 10 with respect to the rejection of claims 10-11 and 15-16 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, of record stated in the Office Action dated November 20, 2002 have been fully considered and found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

Claim Rej ctions - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by CARPINO et al. (WO 98/58947) of record stated in the Office Action dated November 20, 2002.

Claims 1-2, 5-6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by CARPINO et al. (WO 97/24369) of record stated in the Office Action dated November 20, 2002.

Applicant's remarks filed on April 2, 2003 in Paper No. 10 with respect to these two rejections made under 35 U.S.C. 102(b) of record stated in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant argues that WO 98/58947 or WO 97/24369 does not disclose or suggest the instant claimed method for stimulating or increasing appetite in a patient employing the instant compounds of structural formula (I) alone or in combination of a growth hormone secretagogue selected from GHRP-6, GHRP-1, hexarelin and IGF-1, and IGF-II.

As indicated in the previous Office Action, Carpino's methods inherently stimulate or increase appetite in a patient, as claimed herein since Carpino's method steps are

same as the instant method steps. Note that the amount of active compounds to be administered to a patient in instant invention is same as in Carpino et al. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, Carpino's methods for increasing levels of endogenous growth hormone and treating medical disorders associated to deficiency in growth hormone would inherently stimulate or increase appetite in a patient. One of ordinary skill in the art would recognize that the mechanism of action would be increasing growth hormone resulting in stimulating or increasing appetite in a patient by administering the same active agents in the same effective amounts. The examiner's position regarding the mechanism action of increasing growth hormone to stimulate or increase appetite in a patient is supported by the references by Ankersen el al., Murphy et al., and Ghigo et al. (provided by Applicant in PTO-1449) and Vaccarino et al. (CA 2095788, PTO-1449).

With regard to inherency as it related to the claimed invention herein, see also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001).

Thus, Carpino et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-16 even though they are not anticipated by Carpino et al. reference (WO 98/5894 or WO 97/24369) as stated above in the 102(b) rejections, are rejected under 35 U.S.C. 103(a) as being unpatentable over the same references by Carpino et al. in view of Vaccarino et al. (CA 2095788) and The Merck Manual of Diagnosis and Therapy (16th ED) page 1529-1534 of record stated in the Office Action dated November 20, 2002.

Applicant's remarks filed on April 2, 2003 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's argument regarding that Carpino et al. references do not teach or suggest the claimed method herein has been discussed above in the 102(b) rejections. Applicant's argument that Vaccarino et al. does not teach any other growth hormone secretagogue, is not found convincing. Carpino et al. has been cited by the examiner primarily for its teachings that a growth hormone secretagogue or a growth hormone-releasing factor is known to be useful in a method for treating appetite disorder in a patient or stimulating appetite in a patient, which supports the examiner's position in the inherency issue above.

Applicant also asserts that the Merck Manual at page 1533 teaches away from the instant combination in the claimed method. However, the Merck Manual at page 1533 teaches that anorexia, the adverse effect by SSRIs, can occur merely in the first

few months, especially with fluoxetine. It is noted that the instant claims are not limited to the particular antidepressants, SSRIs such as fluoxetine. Moreover, a typical antidepressant is known to be useful in the treatment of depression in a patient suffering from decreasing appetite or anorexia, which is known to one of characteristic symptoms of depression (see the Merck Manual page 1529-1534).

Applicant further argues no motivation to combine the compound herein and an antidepressant. As discussed in the previous Office Action, one of ordinary skill in the art would have reasonably expected that combining the instant compounds of structural formula (I) and (I-A) in combination of an antidepressant herein known to be useful individually for the same purpose, i.e., stimulating or increasing appetite in a patient, in a pharmaceutical composition to be administered would improve the therapeutic effect for stimulating or increasing appetite. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

Claims 17-20 even though they are not anticipated by CARPINO et al. reference (WO 98/5894 or WO 97/24369) as stated above in the 102(b) rejections, are rejected

under 35 U.S.C. 103(a) as being unpatentable over the same references by CARPINO et al. in view of Vaccarino et al. (CA 2095788) and The Merck Manual of Diagnosis and Therapy (16th ED) page 1529-1534, and The Pharmacological Basis of Therapeutics (1996) page 928-932 and 339-430 of record stated in the Office Action dated November 20, 2002.

Applicant's remarks filed on April 2, 2003 in Paper No. 10 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's argument regarding no motivation for the combination herein is not found convincing. As discussed above and in the previous Office Action, one of ordinary skill in the art would have reasonably expected that combining the instant compounds of structural formula (I) and (I-A) in combination of an antiemetic herein or antipsychotic herein known to be useful individually for the same purpose, i.e., stimulating or increasing appetite in a patient, in a pharmaceutical composition to be administered would improve the therapeutic effect for stimulating or increasing appetite. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

Further, the record contains no clear and convincing evidence of nonobviousness or unexpected results for the combinations in the claimed method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
May 30, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

6/2/03